State of California—Health and Human Services Agency
California Department of Public Health

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TO: REPORTING LABORATORIES AND OTHER INTERESTED PARTIES

SUBJECT: ELECTRONIC REPORTING OF QUANTITATIVE HEPATITIS B AND HEPATITIS C NUCLEIC ACID TEST RESULTS IN THE CALIFORNIA REPORTABLE DISEASE INFORMATION EXCHANGE (CALREDIE)

I am writing to describe problems recently identified with electronic laboratory reporting (ELR) of hepatitis-related test results received in CalREDIE, and to request assistance from laboratories in implementing recommendations to address these problems.

Background

California Code and Regulations (CCR) Title 17, Section 2505 requires laboratories to report laboratory results suggestive of specified diseases of public health importance, including acute and chronic hepatitis B and hepatitis C, to the local health department (http://www.cdph.ca.gov/programs/sss/Documents/Title17Sec2505-01-14.pdf). However, Section 2505 only lists the specific diseases and not which laboratory testing results to report. A list of which tests to report is available at the California Department of Public Health (CDPH), Division of Communicable Disease Control website: (http://www.cdph.ca.gov/HealthInfo/Documents/LaboratoryReportableDiseasesInstructionsList-e2.pdf). Specific to hepatitis B and hepatitis C, reportable tests include, but are not limited to:

- Nucleic acid test (NAT) for hepatitis B virus (HBV) deoxyribonucleic acid (DNA) positive (including qualitative, quantitative and genotype testing)
- NAT for hepatitis C virus (HCV) ribonucleic acid (RNA) positive (including qualitative, quantitative or genotype testing)

Recently, several local health jurisdictions (LHJs) have identified challenges with hepatitis-related NAT results automatically imported into CalREDIE via ELR. Problems have included receiving results that were clearly negative (and thus should not have been reported) and results with incomplete information needed to interepret the test result as negative or positive. Without this information, LHJs are unable to determine whether the test results reported are suggestive of a disease reportable under Title 17, CCR Section 2505 for public health surveillance purposes. This letter summarizes findings and recommendations from a fall 2014 CDPH investigation into these problems, which included data analysis and a call with high-volume laboratories.

Findings

From June 29, 2014 – September 29, 2014, CalREDIE received 21,777 hepatitis B and hepatitis C-related ELR messages, of which 12,977 (60%) were NAT results (excluding genotype tests). Among NAT results received, 3,695 (28%) were negative or unclear:

- 1,434 (39%) were clearly negative (i.e., the result field stated that the virus was "not detected" or "undetected")
- 1,856 (50%) were below the lower limit of detection or quantification (e.g., <15); it was not consistently noted whether the virus was detected or not detected
- 403 (11%) had a low numerical value (e.g., 20) but lacked further information needed to interpret the result (e.g., a less than (<) sign; a reference range; or an interpretative statement)
- 2 (<1%) were missing or uninterpretable

Some laboratories are unable to report whether the virus was detected because their testing systems do not generate this information. Others report quantitative hepatitis NAT results below the lower limit of detection as positive because quantitative NATs are only approved by the U.S. Food and Drug Administration for patient monitoring (prognosis) and not for diagnosis. However, laboratories may use quantitative NATs for diagnosis if they have performed appropriate validation studies (http://www.aphl.org/AboutAPHL/publications/Documents/ID_2013Dec_Testing-For-Hepatitis-C-Viral-Infections-FAQS.pdf), and many laboratories have done so.

Recommendations

1) NAT results for hepatitis B and hepatitis C that are clearly negative (i.e., the virus was "not detected") should **not** be submitted via ELR. (However, LHJs and CDPH may still request negative NAT results when conducting hepatitis-related case investigations.)

2) Quantitative NAT result reports should include, at minimum:

a) A note that the virus was detected AND
b) Either of the following:
   i) A numeric value (e.g., XXXXX IU/mL) OR
   ii) A sign (e.g., <) and numeric value (e.g., <XX IU/mL) indicating the virus was below the lower limit of quantification (LLQ) OR
   iii) A text result indicating the virus was below the LLQ

For example, positive quantitative HCV RNA test results should be reported as either:

-- HCV RNA detected - XXXXX IU/mL **OR**
-- HCV RNA detected - <XX IU/mL **OR**
-- HCV RNA detected - Below the lower limit of quantification

Thank you for your assistance in improving viral hepatitis-related ELR. If you have questions about laboratory reporting, please contact the CalREDIE ELR help desk at ELR@cdph.ca.gov. If you have further questions about hepatitis reporting, please contact me by email at Rachel.McLean@cdph.ca.gov or by phone at (510) 620-3403.

Sincerely,

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